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ELEVATE ANTERIOR AND APICAL IN THE TREATMENT OF PELVIC ORGAN PROLAPSE: TWO-YEAR FOLLOW-UP

Hypothesis / aims of study
To assess safety and efficacy of the Elevate® Anterior and Apical (EAA) with IntePro® Lite™ support system (American Medical Systems, Minnesota, USA) in the repair of pelvic organ prolapse (POP). We present two-year post procedure data.

Study design, materials and methods
One hundred and forty-two women (age 63.9 ± 9.8 years) were enrolled at 16 investigational sites (10 US, 6 EU) of which 124 (87.3%) completed 24-month follow-up. Of the 18 subjects who did not complete the 24-month visit, 10 were lost to follow up, 5 voluntarily withdrew consent, 1 had device removed and 2 died (unrelated to either device or procedure). The primary outcome was surgical treatment success using 2 definitions: 1) Objective anatomic success defined as ≤ Stage I POP-Q during follow-up using the Last observed Failure Carried Forward (LFCF) method. The LFCF method carries forward a patient's objective failure at previous visits if their 24-month results were missing. It also considers subjects to be failures if they were re-operated for recurrent prolapse in the anterior or apical segments within 24 months from the initial implant regardless of their POP-Q test results. Subjects who had a concomitant Elevate Apical and Posterior repair were excluded from the apical efficacy analysis. 2) Subjective cure defined as the absence of bulge symptoms (negative response to Pelvic Floor Distress Inventory (PFDI) questions 'Do you usually have a sensation of bulging or protrusion from the vaginal area?' (Q4) and 'Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?' (Q5)). Secondary outcomes were quality of life (QOL) measures using Pelvic Organ Prolapse Urinary Incontinence Sexual Function Questionnaire (PISQ-12), Pelvic Floor Impact Questionnaire (PFIQ), and Pelvic Floor Distress Inventory (PFDI) questionnaires. Wilcoxon signed rank test and paired t-test were used to compare continuous measurements from baseline through 24 months as appropriate. The exact 95% confidence interval of the anatomic success rates was calculated using the binomial method. Statistical significance was assessed at p-value < 0.05.

Results
The objective anatomic success rate for the anterior compartment was 81.6% (102/125, 95% CI 73.7-88.0%). Of the 23 subjects considered failure per LFCF, none complained of bulging on the PFDI. The anatomic success rate for the apical compartment was 95.9% (71/74, 95% CI 88.6-99.2%). Of the 3 subjects who presented with apical anatomic failure only one complained of bulge symptoms and one subject had her study device removed due to recurrence of cystocele. Tables 1 and 2 list POP-Q results. There were 8 (5.6%) mesh extrusions all resolved but one (subject was lost to follow up). Treatment included trimming in the office (3/8), excision in the operating room (3/8), topical estrogen (1/8), and resolution without treatment (1/8). Other related adverse events reported at >2% were urinary tract infection (8; 5.6%), dyspareunia (7; 4.9%), de novo urinary stress incontinence (6; 4.2%), transient buttock pain (5; 3.5%), new prolapse (5, 3.5%), urinary retention (5; 3.5%), granuloma formation (4; 2.8%), hematoma (3; 2.1%) and urinary urgency (3, 2.1%). All QOL scores were significantly improved from baseline (p<0.001). PISQ-12 score improved by a mean of 4.3±6.3 with 80.0% (36/45) of the subjects who completed this questionnaire at baseline and at 24 months reporting improvement concerning sexual function. Satisfaction scores revealed that 120 (96.8%) felt they were some or a lot improved and 116 (93.5%) were moderately, very, or extremely satisfied.

Interpretation of results
Two year data show that the Elevate Anterior and Apical support procedure completed through a single vaginal incision and no external needle passes yields objective and subjective improvement with few complications. It also demonstrates low mesh extrusion rates and high patient satisfaction.

Concluding message
EAA yields favourable objective and subjective outcomes with few complications.

Table 1	Apical 24 month			Anterior 24 month		
Baseline Stage	N Patients	N Success	% Success	N Patients	N Success	% Success
2	39	37	94.9%	32	28	87.5%
3/4	35	34	97.1%	93	74	79.6%
Total	74	71	95.9%	125	102	81.6%

Table 2	Baseline (n=122)		24 month (n=122)		P-value (Wilcoxon)
POP-Q Point	Mean ± sd	95% CI	Mean± sd	95% CI	
Aa	1.2 ±1.3	0.9 - 1.4	-2.2 ±1.0	-2.4 - -2.0	<0.001
Ba	2.7 ±1.9	2.3 - 3.0	-2.2 ±1.0	-2.3 - -2.0	<0.001
C*	-0.3 ± 3.7	-1.0 - 0.4	-7.2 ± 1.8	-7.4 - -6.7	<0.001**

Total Vaginal Length	8.5 ±1.1	8.3 - 8.7	8.5 ±1.1	8.3 - 8.7	0.839
* n=110, subjects who had a concomitant Elevate Apical and Posterior were not included in the analysis ** paired t-test					

Disclosures
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2.Western Institutional Review Board
3.Medisch Ethische Commissie Academisch Medisch Centrum Universiteit van Amsterdam
4.Northside Hospital IRB
5.Leuven University Hospital
6.Allina Institutional Review Board Administrative Office
7.Consorci Santari Integral **Helsinki:** Yes **Informed Consent:** Yes